

REMARKS

1. THE AMENDMENTS TO THE CLAIMS

Before this Amendment, claims 22-25, 27 and 30-33 were pending. Claims 22-25, 27 and 31-33 will be pending and under active consideration upon entry of this Amendment. Claim 30 has been canceled without prejudice. Applicants expressly reserve the right to prosecute claims drawn to any subject matter canceled or removed by amendment in related applications.

Claims 22-24 and 31-33 have been amended to more particularly point out and distinctly claim the subject matter of certain embodiments of the invention. No new matter is added by these amendments, and they are believed to place the claims in condition for allowance. The subject matter of the claims, as amended, is fully supported in the specification and claims as originally filed. Accordingly, entry thereof into the instant application is respectfully requested.

In particular, Claims 22 and 24 have been amended to incorporate the limitations of canceled claim 30, and to recite a transgenic plant comprising a transgene encoding a heterologous gene of interest operatively associated with a *SHORT-ROOT* promoter, said promoter consisting essentially of a nucleic acid sequence of SEQ ID NO:4. Support for this amendment to claims 22 and 24 may be found, *inter alia*, at page 7, lines 20-25; page 41, line 30 to page 42, line 16; and page 56, lines 9-14. As recited in the specification,

[i]n the context of gene constructs, a heterologous gene means that the gene is linked to a promoter that said gene is not naturally linked to. The heterologous gene may or may not be from the organism contributing said promoter. The heterologous gene may encode messenger RNA (mRNA), antisense RNA or ribozymes[.]

(page 7, lines 20-25; emphasis added). Non-limiting, illustrative examples of heterologous genes and/or proteins that are recited in the specification may be found *inter alia*, at page 6, lines 1-2 (heterologous reporter gene); page 12, lines 23-33 (lysozymes, cecropins, maganins, thionins, glucanases, chitinases, *Bacillus thuringiensis* endotoxins, protease inhibitors, collagenases, lectins, and glycosidases); page 27, lines 7-17 (epitope that is recognized by commercially available antibody, immunoglobulin constant domain, cell surface molecule which anchors a fusion protein to a cell membrane, detectable label such as a fluorescent protein or enzyme); page 56, lines 22-23 (starch, lignin and cellulose); page 63, lines 28-34

and page 66, lines 32-35 (β -glucuronidase (GUS) coding region); and page 64, lines 6-8 and page 66, lines 32-35 (Green Fluorescent Protein (GFP) coding region).

Claim 23 has been amended to depend from claim 22, rather than from canceled claim 21. Support for this amendment to claim 23 may be found, *inter alia*, at page 12, lines 23-33; and page 56, lines 9-18.

Claim 31 has been amended to recite an isolated nucleic acid molecule consisting essentially of a nucleic acid sequence of SEQ ID NO:4. Support for this amendment to claim 31 may be found, *inter alia*, at page 5, line 32 to page 6, line 4; page 7, lines 7-9; page 41, line 30 to page 42, line 16; page 42, lines 11-16; and in Figure 11.

Claims 32 and 33 have been amended to recite an isolated nucleic acid molecule comprising a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter, which promoter consists essentially of the nucleic acid sequence of SEQ ID NO:4. Support for this amendment to claims 32 and 33 may be found, *inter alia*, at page 5, line 32 to page 6, line 4; page 7, lines 7-9; page 41, line 30 to page 42, line 16; page 42, lines 11-16; and in Figure 11.

A marked up version of the claims showing the amendments made herein is attached hereto as Appendix A.

2. CLAIM OBJECTION

Claim 23 is objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 23 is drawn to transgenic plant in which the gene of interest encodes a gene product that confers herbicide, salt, pathogen, or insect resistance. Claim 23 has been amended to depend from claim 22 (wherein the gene of interest is expressed in a tissue-specific manner in roots or embryos) rather than from canceled claim 21, thus obviating the objection.

3. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF WRITTEN DESCRIPTION SHOULD BE WITHDRAWN

Claims 22-25, 27 and 32-33 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter alleged to be not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The rationale of the rejection is set forth on pages 3-4 of the Office Action. The Examiner recognizes that the specification discloses a SHORT-ROOT (SHR) promoter, SEQ ID NO:4 that has promoter function in transgenic *Arabidopsis* roots and embryos. The Examiner alleges, however, that the structural and physical features of the claimed transgenic plants and isolated nucleic acid molecules cannot be ascertained in the absence of information about the functional activity of the nucleic acid molecules that they comprise, and that the specification does not disclose whether any nucleic acid molecule other than SEQ ID NO:4 will function as a promoter. As originally submitted, these claims recite, respectively, that the isolated nucleic acid promotes stele-specific expression.

Without acquiescing to the propriety of the rejection of claims 22-25, 27 and 32-33, and solely to advance prosecution and obtain coverage for certain embodiments of the invention, Applicants have amended claims 22, 24, 32 and 33. Applicants fully reserve all rights to argue against the rationale of the rejection and to pursue the subject matter deleted by amendments made herein in a subsequent continuation application. Applicants have amended independent claims 22 and 24 to recite that *SHORT-ROOT* promoter consists essentially of a nucleic acid sequence of SEQ ID NO:4. Applicants have amended independent claims 32 and 33 to recite that the isolated nucleic acid molecule comprises a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter which consists essentially of the nucleic acid sequence of SEQ ID NO:4. As originally submitted, these claims recite, respectively, that the isolated nucleic acid promotes stele-specific expression in root and hypocotyl.

It is submitted, based on the foregoing, that the rejection of claims 22 and 24 (and claims 23, 25 and 27 depending therefrom) and claims 32-33 under 35 U.S.C. § 112, first paragraph, for lack of written description, has been obviated. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

4. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF ENABLEMENT SHOULD BE WITHDRAWN

Claims 22-25, 27 and 30-33 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner alleges that the specification, while being enabling for a nucleic acid sequence of SEQ ID NO:4, and a transgenic *Arabidopsis* plant comprising a gene of interest operatively associated with a *SHORT-ROOT* promoter of SEQ ID NO:4, does not

reasonably provide enablement for other promoter sequences, or other plants comprising other promoter sequences and therefore, does not provide enablement commensurate in scope with these claims.

Applicants respectfully disagree. With respect to the allegations in the Office Action, Applicants assert that the claims are enabled and that the specification fully teaches one skilled in the art how to make and use the recited *SHORT-ROOT* promoter sequences. Without acquiescing to the propriety of the rejection of claims 22-25, 27 and 30-33, and solely to advance prosecution and obtain coverage for certain embodiments of the invention, Applicants have amended claims 22, 24 and 31-33. Applicants fully reserve all rights to argue against the rationale of the rejection and to pursue the subject matter deleted by amendments made herein in a subsequent continuation application.

Claims 22 and 24 (and claims 23, 25 and 27 depending therefrom) have been amended to recite that *SHORT-ROOT* promoter consists essentially of a nucleic acid sequence of SEQ ID NO:4, so that the gene of interest is expressed in a tissue-specific manner in roots or embryos (claim 22) or in shoots (claim 24). This sufficiently describes the claimed transgenic plants so that a skilled artisan would be enabled to make and/or use the claimed invention.

Claim 31 has been amended to recite that the isolated nucleic acid molecule consists essentially of a nucleic acid sequence of SEQ ID NO:4. This sufficiently describes the claimed nucleic acid molecule so that a skilled artisan would be enabled to make and/or use the claimed invention.

Claims 32 and 33 have been amended to recite that the isolated nucleic acid molecule comprises a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter, which promoter consists essentially of the nucleic acid sequence of SEQ ID NO:4 and promotes stele-specific expression in root (claim 32) or hypocotyl (claim 33), and wherein the high stringency conditions comprise washing in a solution composed of 2X SSC, 0.01% PVP, 0.01% Ficoll, and 0.01% BSA at 68°C. Applicants submit that the skilled artisan would recognize washing conditions in a nucleic acid hybridization reaction as the critical feature for the stringency of the hybridization, and moreover, that the skilled artisan would be able to recognize the molecule of the invention based on the well known relationship between nucleic acid structure (*i.e.*, sequence) and hybridization. The skilled artisan would recognize the claimed nucleic acid molecule by its

size, its ability to hybridize over its full length under high stringency conditions to a *SHORT-ROOT* promoter which promoter consists essentially of the nucleic acid sequence of SEQ ID NO:4, and its function of promoting stele-specific expression in root or hypocotyl. Hence, Applicants submit that the claimed nucleic acid molecule is sufficiently described so that a skilled artisan would be enabled to make and/or use the claimed invention.

According to applicable case law, under 35 U.S.C. § 112, an invention is enabled even though the disclosure may require some routine experimentation to practice the invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986). Considerable amount of experimentation is permitted if it is merely routine or the specification provides reasonable amount of guidance and direction to the experimentation. *In re Jackson*, 217 U.S.P.Q. 804, 807 (1982).

The specification fully teaches how to isolate a transgenic plant comprising a transgene encoding a heterologous gene of interest operatively associated with a *SHORT-ROOT* promoter using methods routinely achieved in the art (see specification at pages 56-58). The specification fully teaches how to isolate a nucleic acid molecule encoding a *SHR* promoter under hybridization conditions routinely achieved in the art (see specification at pages 41-43). Where a disclosure provides considerable direction and guidance on how to practice the invention, and where, at the time of the application, the skill in the art was quite high and the methods needed to practice the invention well known, a conclusion of enablement should be made. *In re Wands*, 858 F.2d 731, 740, 8 U.S.P.Q.2d. 1400, 1406 (Fed. Cir. 1988). Here, the specification provides reasonable amount of guidance and direction for making and using the claimed transgenic plants and promoter sequences, hence the invention is enabled.

Furthermore, contrary to the Examiner's allegation, the specification teaches that the *SHR* has promoter function and drives expression of reporter genes (GFP) and β -glucuronidase (GUS) in mature embryonic *Arabidopsis* shoots (see specification at page 64, lines 6-8 and page 66, lines 32-35 (green fluorescent protein (GFP)); at page 63, lines 28-34 and page 66, lines 32-35 (β -glucuronidase (GUS)); Figure 4F and figure legend at page 10, lines 6-11). A skilled artisan, armed with the teachings of the specification, would conclude correctly that the *Arabidopsis SHR* promoter, *i.e.*, SEQ ID NO:4, therefore has promoter function in *Arabidopsis* shoots because the *SHR* gene product is expressed there in wild-type embryos.

The Examiner alleges that the specification does not teach whether a transgenic plant containing any gene of interest operatively associated with the *SHR* promoter (SEQ ID NO: 4) is less susceptible to lodging. Applicants respectfully disagree. Applicants respectfully point out that claim 25 is drawn to the transgenic plant of claim 23, in which the gene of interest encodes a gene product that increases starch, lignin or cellulose biosynthesis. Claim 27 is drawn to the plant of claim 25, which is less susceptible to lodging than a wild-type plant. Two types of lodging, which are well known to the skilled artisan, may occur in a plant: stem breakage and root lodging. Contrary to the Examiner's allegation, the specification teaches that genes that may be beneficially expressed in the stems of plants include those involved in starch, lignin or cellulose biosynthesis (see specification at page 56, lines 22-23). One of ordinary skill in the art would instantly recognize that the increased synthesis of starch, lignin or cellulose in stems (or roots) of plants would be beneficial because increased synthesis of such products in the stem (or root) of a plant would normally be expected to strengthen the stem (or root) so that it would be less susceptible to breakage. In either case (increased synthesis in stems or roots), the skilled artisan would recognize that the plant would be less susceptible to lodging than a wild-type plant. Specifically, the skilled practitioner would recognize that increased synthesis of starch in a tissue-specific (*i.e.*, stele-specific) manner in the root would affect secondary root formation and the likelihood of root lodging. The skilled practitioner would recognize that increased synthesis of lignin (and lignification) in a tissue-specific (*i.e.*, stele-specific) manner in the stem would affect stem strength and the likelihood of stem breakage. The skilled practitioner would also recognize that increased synthesis of lignin (and lignification) in a tissue-specific (*i.e.*, stele-specific) manner in the stem would affect stem strength and the likelihood of stem breakage. The skilled practitioner would also recognize that increased synthesis of cellulose in a tissue-specific (*i.e.*, stele-specific) manner in the stem or root would affect cell wall formation and the strength of sieve elements, and thus the likelihood of stem breakage or root lodging.

It is submitted, based on the foregoing, that the above rejections of claims 22-25, 27 and 30-33 under 35 U.S.C. § 112, first paragraph, for lack of enablement, have been obviated. Accordingly, Applicants respectfully request that these rejections be reconsidered and withdrawn.

5. THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, FOR INDEFINITENESS SHOULD BE WITHDRAWN

Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as indefinite with respect to the term "containing." Claim 22 has been amended to delete recitation of "containing" and to recite a transgenic plant comprising a transgene encoding a heterologous gene of interest operatively associated with a *SHORT-ROOT* promoter consisting essentially of a nucleic acid sequence of SEQ ID NO:4, so that the gene of interest is expressed in a tissue-specific manner in roots or embryos, thus obviating the rejection of claim 22. Accordingly, Applicants respectfully request that this rejection for indefiniteness be reconsidered and withdrawn.

6. THE REJECTION UNDER 35 U.S.C. § 102(b) FOR ANTICIPATION SHOULD BE WITHDRAWN

Claims 31-33 are also rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Bevan *et al.* (GenBank Accession No. AL035605, dated March 4, 1999, direct submission of March 3, 1999; Exhibit 1). Bevan *et al.* discloses the *Arabidopsis thaliana* DNA chromosome 4, BAC clone F19F18 sequence. Bevan *et al.*, however, does not disclose an isolated nucleic acid molecule consisting essentially of a nucleic acid sequence of SEQ ID NO:4. (claim 31). It does not disclose an isolated nucleic acid molecule comprising a nucleic acid sequence which hybridizes over its full length under high stringency conditions to a *SHORT-ROOT* promoter which consists essentially of the nucleic acid sequence of SEQ ID NO:4 and promotes stele-specific expression in root (claim 32) or hypocotyl (claim 33), and wherein the high stringency conditions comprise washing in a solution composed of 2X SSC, 0.01% PVP, 0.01% Ficoll, and 0.01% BSA at 68°C.(claims 32-33). Accordingly, Bevan *et al.* does not anticipate claims 31-33 and Applicants respectfully request that this rejection be reconsidered and withdrawn.

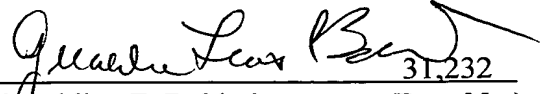
CONCLUSION

Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the file history of the present application. Withdrawal of the Examiner's rejections and a notice of allowance are earnestly requested. If any issues remain

in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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Attachments:

Appendix A: Marked up version of the amended claims

Exhibit 1: Bevan *et al.*, GenBank Accession No. AL035605, dated March 4, 1999.